

Meeting between FCC Office of Engineering and Technology and Biotronik

Regarding Biotronik Comment to NPRM
(ET Docket Nos. 06-135 and 05-213; RM-11271)

Attendees from Biotronik

Dr. Larry Stotts – Executive VP Research & Development

Jim Nelson – Senior Director Technology Development

Paul Stadnik – Manager RF group

Henry Goldberg – Attorney for Biotronik

Laura Stefani – Attorney for Biotronik

May 23, 2007

Agenda

- Introduction
- Benefits of a Beacon Channel
- Optimal Placement for LP-LDC Channel is the Center of MICS Band
- LP-LDC Results in Virtually no Harmful Interference
- Industry Consensus Supports LP-LDC in MICS Band
- Conclusion

Over 60,000 BIOTRONIK Home Monitoring Systems have been implanted in 25 countries worldwide

- The FCC Waiver continues to benefit patients: Over 20,000 BIOTRONIK Home Monitoring Systems have been implanted in the US
- Pacemakers, Implantable Cardioverter Defibrillators and CHF devices ... with no reports of interference.
- These implants have generated over 5 million successful transmissions

Biotronik Bi-Directional Implants



Biotronik has launched a bi-directional implant: Biotronik LUMAX™ ICD

- FCC Approval: December 2006
- FDA Approval: January 2007
- Product Launch: February 2007

There is a place for both access methods:
LBT and Low Power – Low Duty Cycle (LP-LDC)

Low Power – Low Duty Cycle

- Low Power – Low Duty Cycle (LP-LDC)
 - Access method
 - Limits power and duty cycle of transmissions
 - Supplements the existing LBT / AFA regulations
- Recognized need for this technology
 - Included in FCC NPRM
 - Included in international standards¹
 - Significant industry support as evidenced by NPRM Comments

1. Canada, Europe and Australia allow LP-LDC in the MICS Band

LP-LDC in the MICS Band

- Biotronik strongly supports aligning the LP-LDC regulations with international standards
- Create an LP-LDC access method within the existing MICS Band.
 - Low Power: 100 nW erp
 - Low Duty Cycle: 0.01% measured per hour
 - Center Frequency: 403.65 MHz
 - Bandwidth: 300 kHz

Beacon Channel – A Key Application of LP-LDC

- Allows the implant to initiate transmissions
 - Allows implant driven events
 - Resolves clock drift issues
- Benefits
 - Less band clutter due to fewer overall transmissions
 - Increased throughput due to simplified protocol
 - Longer implant life due to less battery consumption
 - Less latency between request for communication and transmission of data
 - Ease of patient use: device initiates communication automatically

Initiation of RF session using LBT

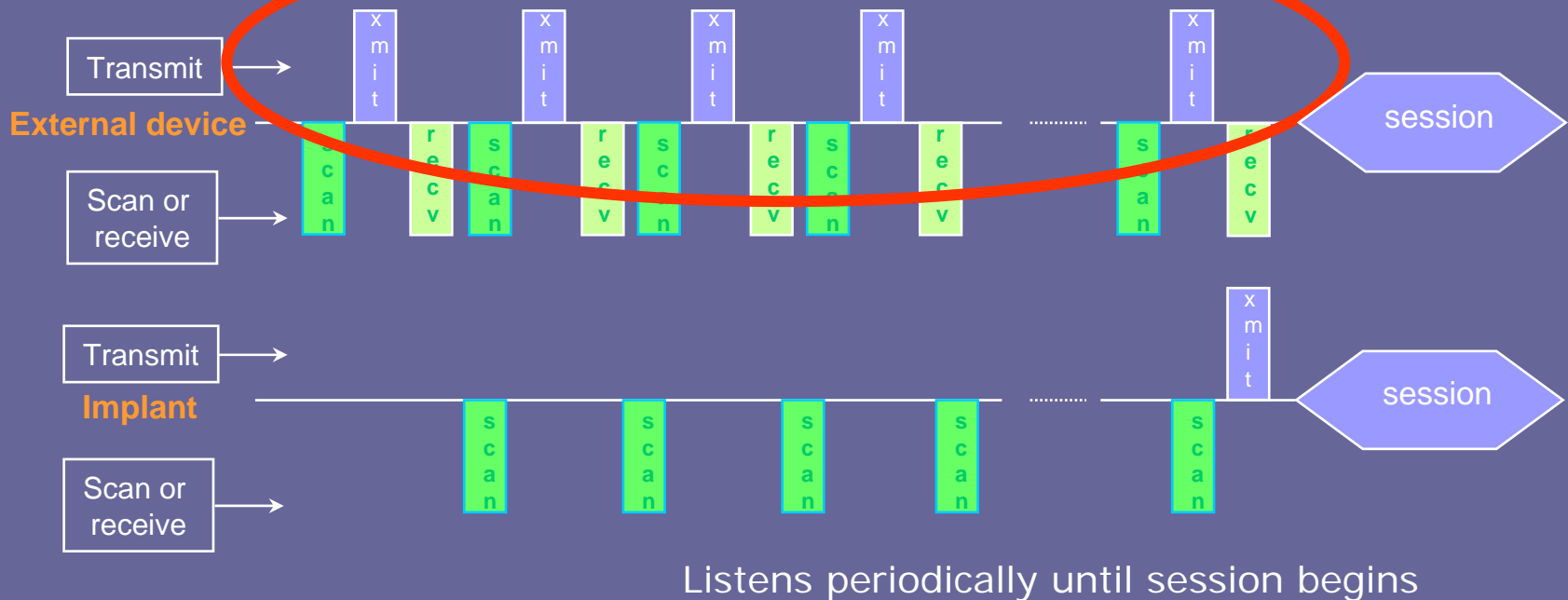
LBT

Scans, and broadcasts on Least Interfered Channel (LIC) for 5 seconds.

Listens on LIC for 5 seconds.

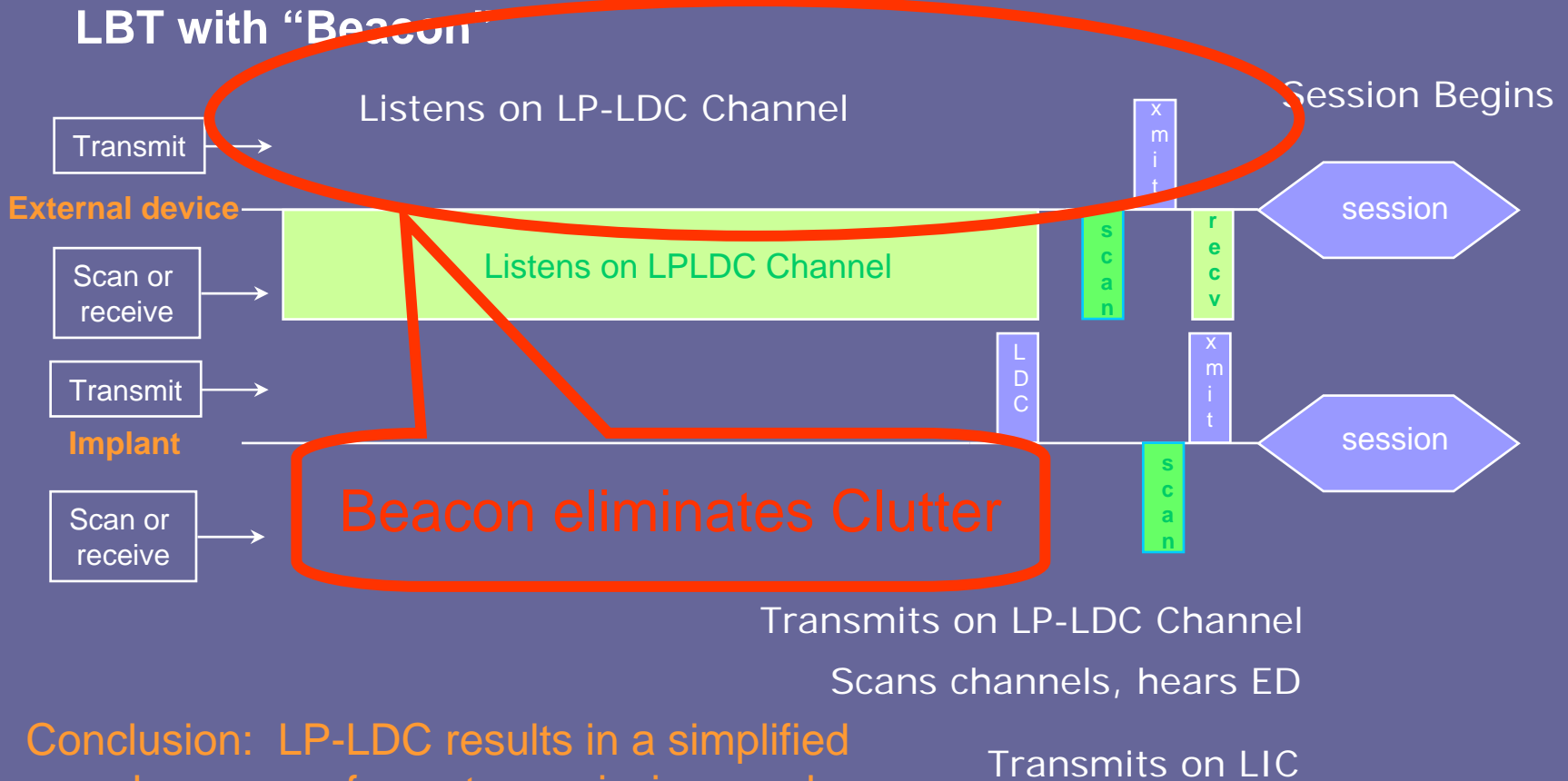
Band Clutter

Session Begins



Conclusion: LBT requires additional RF transmissions during search and additional current drain from implant

Initiation of RF session using LP-LDC "Beacon"



Conclusion: LP-LDC results in a simplified search process, fewer transmissions and better implant longevity

Beacon Channel: REAL Benefits!

- Adding a beacon channel capability to the MICS regulations will provide significant benefits to the user community, including increased reliability, decreased transmission latency and longer implant life while freeing the band of extraneous and unnecessary transmissions.
- These very real benefits will drive new applications dependent on implant driven events.

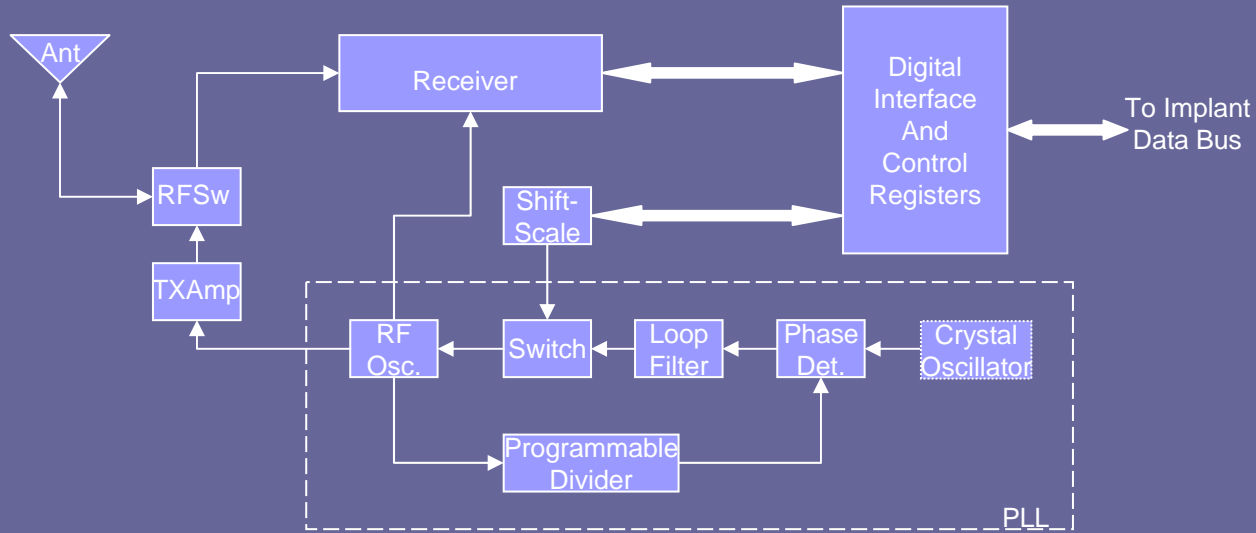
Optimal Placement for LP-LDC Channel

Q Where should the LP-LDC Channel be located to realize these benefits?

A Placing the LP-LDC channel in the center of the MICS band provides advantages to both classes of devices expected to use LP-LDC:

- Beacon capable devices
- LP-LDC (only) devices

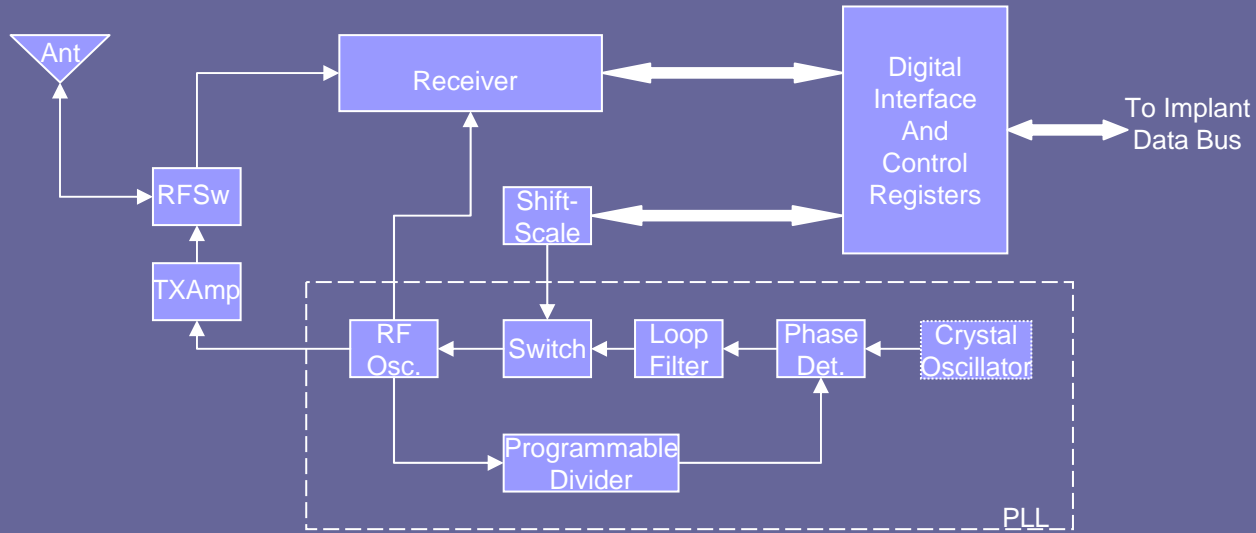
MICS Implant Transceiver: LBT System



- An LBT implementation with Adaptive Frequency Agility requires the components identified here.
- Current consumption during transmission is up to 24 mA²

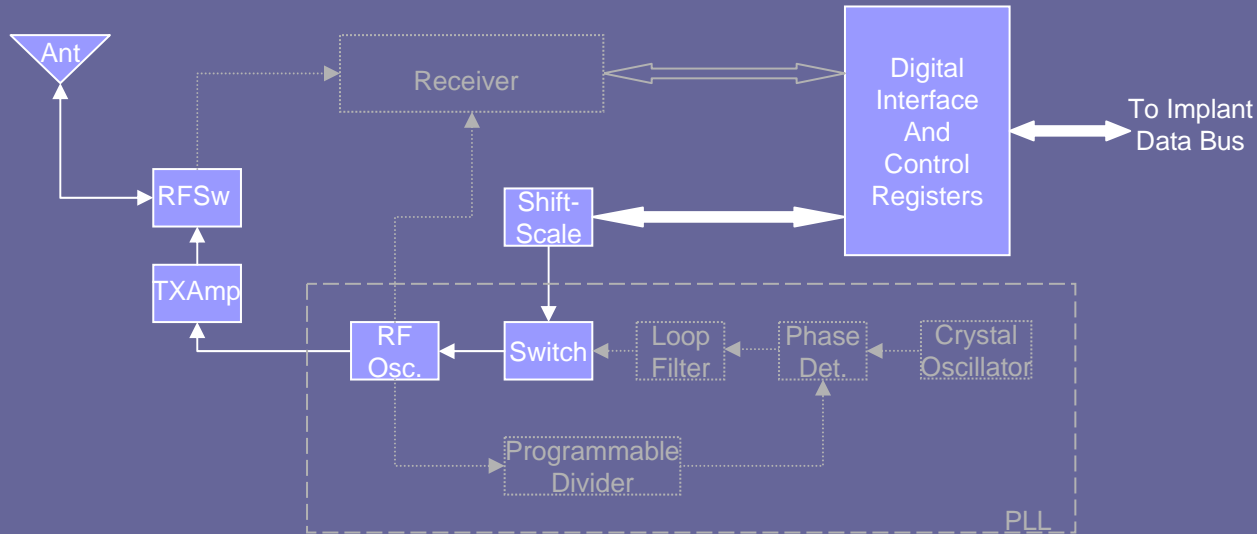
2. AMIS-53000 data sheet, Aug 05 Rev 1.0

MICS Implant Transceiver: LP-LDC in Wing Band



- A Dual-Use system (LBT/AFA with LP-LDC limited to the wing bands) requires the same components.
- Current consumption during transmission is up to 24 mA

MICS Implant Transceiver: LP-LDC in MICS Band



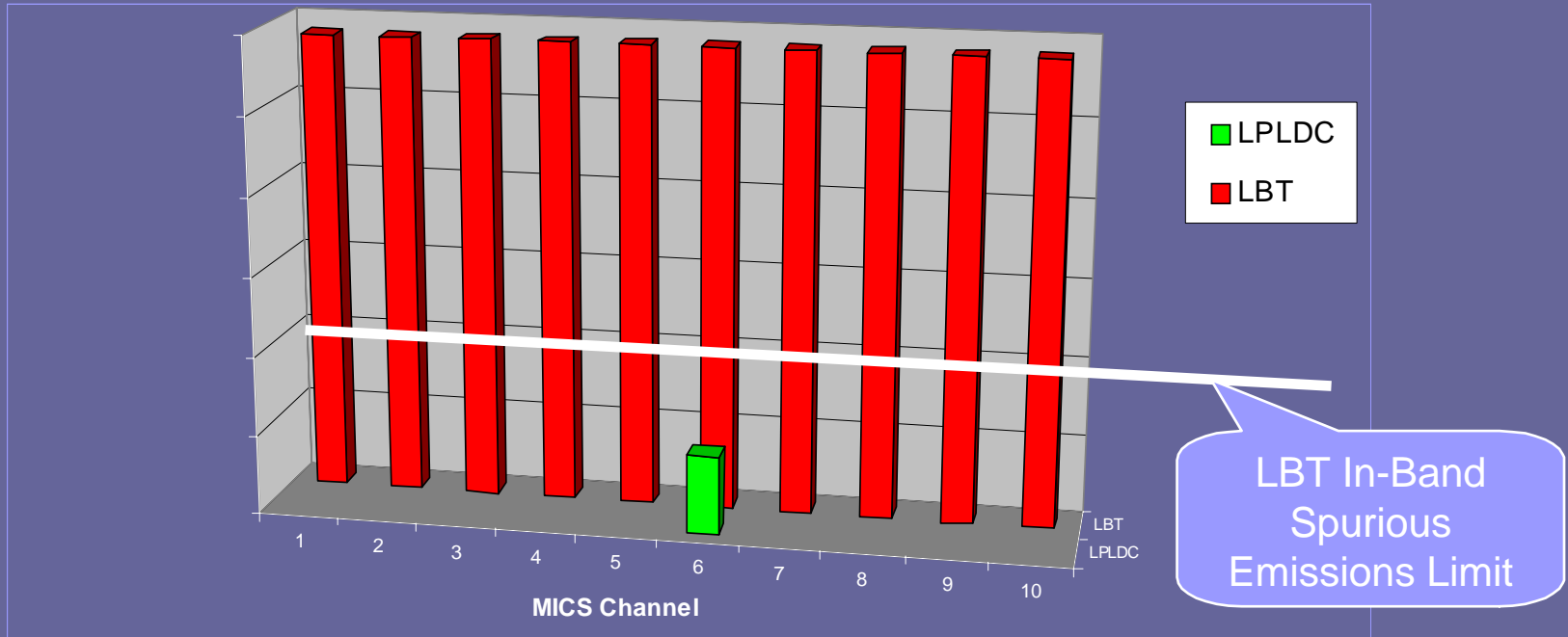
- A Dual-Use system can power down the grayed components during beacon or LP-LDC transmissions.
- An LP-LDC system can eliminate the grayed components and benefit from design reuse.
- Current consumption during transmission is 2.8 mA³

LP-LDC Interference Analysis

- Interference between two or more LP-LDC systems has been shown to be virtually non-existent. (As demonstrated by Biotronik experience and presented in earlier FCC filings)
- RF analysis and simulation tools (e.g. Seamcat-3) can be used to predict the probability of interference between LP-LDC and LBT systems.
- The results of this analysis⁴ confirm that interference between systems using LBT and systems using LP-LDC (.01% duty cycle) is extremely unlikely (probability on the order of 9×10^{-6})
- The nature of the MICS band requires that all systems include mitigation techniques that virtually eliminate any harmful effects of interference.

4. Biotronik FCC *ex-parte* notice 25 September 2006  **BIOTRONIK**

Transmit Power Distribution: MICS Channels



The low power translates into the 9.96×10^{-6} probability of interfering with MICS users even if there are many LPLDC systems in the vicinity.

Industry Consensus Supports LP-LDC in MICS



Industry Consensus:



- Biotronik supports a duty cycle of 0.01% consistent with ETSI⁵ and the industry consensus as evidenced by NPRM Comments.
- The ETSI Standard is likely to be approved June 2007.
- The ETSI Standards will allow LP-LDC in both the MICS Band and the Wing Bands.
- Our simulations⁶ have shown that harmful interference is virtually non-existent for duty cycles up to ten times higher than this proposed limit.

5. ETSI EN 301 839-1 V1.2.1 (2006-05)

6. Biotronik FCC *ex-parte* notice dated 25 September 2006

Industry Consensus:



- *"St. Jude Medical strongly believes that an additional access method to the MICS band should be enabled. An ultra low duty cycle access (0.01%) that can be used by MICS implants only on the center channel: 403.5 – 403.8 MHz with limited output power: 100 nW e.r.p, as an interference reduction technique for mutual in-band interference."* ⁷
- *"LBT/AFA is not a technically suitable method for the implant to access the MICS band due to technical limitations. The ultra low duty cycle access via the centre channel in the MICS band enables the implant to initiate communication with an external unit. It is essential that the ultra low duty cycle access only be allowed on one channel in the middle of the protected MICS band while minimizing risk of interference with other medical equipment ."* ⁸

7. St. Jude NPRM Comment #1 dated 27 October 2006

8. Ibid

Industry Consensus:



- *"AMIS also supports the proposal by Biotronik to allow low power/low duty cycle operation in the centre of the current MICS band 403.65 MHz +/- 150 kHz." ⁹*
- *"This is in harmony with ETSI directions and will simplify the establishment of communications between devices. This proposal will increase the deployment of MICS band devices, allowing a larger number of patients to benefit from this technology." ⁹*
- *The very low duty cycle mode of operation proposed for the "wing" band as well as the 403.65MHz channel pose little risk of interference with LBT MICS devices due to the difference in frequency assignments and low duty cycle for the "beacon mode". ¹⁰*

9. AMIS NPRM Comment #6 dated 30 October 2006

10. AMIS Reply page 2 dated 29 November 2006

Industry Consensus:



- *“DexCom supports the proposal to permit the operation of low-duty cycle medical devices that do not have frequency monitoring capability, but such devices should not be subject to unnecessary stringent power restrictions and should be permitted in the entire 401-406 MHz band rather than being limited to the wing bands.”¹¹*

11. DexCom, Inc. NPRM Comments page 3 dated 31 October 2006

Industry Consensus:

Boston
Scientific

GUIDANT

- *“BSCCRM disagrees with the Medtronic approach and, instead, agrees with the comments of Biotronik, Inc. and DexCom that a two-tiered structure for an expanded MICS band to accommodate body-worn devices is unnecessary and ill-advised.”*¹²
- *“BSCCRM believes that the LBT requirement adversely impacts the use of the MICS band and should not be mandated. The implementation of LBT burdens devices with a complex and computation-intensive protocol that significantly increases both the receiver and protocol complexity that an implanted device must support to communicate with an external device.”*¹³

12. Boston Scientific NPRM Comments page 2 dated 31 October 2006

13. Ibid, page 11

Industry Consensus:



- *"... should the FCC decide to permit LPLDC operations in the MICS band, it should follow the terms of the proposal in Europe [ETSI EN 301 839-1 V1.2.1 (2006-05)] as set forth by St. Jude Medical and Zarlink Semiconductor."*¹⁴
- Medtronic will need to comply with the MICS Band regulations in Europe.
- In Europe, LP-LDC will be allowed in both the MICS Band as well as the Wing Bands.
- Manufacturers should have the same flexibility in the US.

14. Medtronic, Inc. NPRM Reply Comments page 14 dated 4 December 2006

Conclusion

- The public is well served with the addition of LP-LDC as an access method to supplement LBT-AFA in the MICS Band.
- A Beacon Channel is a key application for LP-LDC.
- The optimal location for the LP-LDC channel is the center of the MICS Band.
- Harmful interference is virtually non-existent.
- Although there are differences between each manufacturer in their replies, there is clearly a consensus around allowing LP-LDC in the MICS Band.

Suggested Regulatory Changes: LP-LDC Access

§ 95.628 MICS Transmitter

(b) Exceptions to access criteria in (a).

- 1) MICS communications sessions initiated by a medical implant event are not required to use the access criteria set forth in paragraph (a) of this section.
- 2) Transmissions from a Medical Implant Transmitter are not required to use the access criteria set forth in paragraph (a) of this section so long as the transmit power is not greater than 100 nanowatts EIRP and the duty cycle for such transmissions does not exceed 0.01%, based on the total transmission time during a one-hour interval. A Medical Implant Transmitter operating under the exception in this subsection (b)(2) may only transmit on the frequencies identified in §95.628(c).

(c) Stations that incorporate the access criteria set forth in paragraph (a) of this section may operate on any of the frequencies in the band 402.000 - 405.000 MHz, provided that the out-of-band emissions are attenuated in accordance with § 95.635. Stations that operate under paragraph (b) of this section may operate on any of the frequencies in the band 403.500 - 403.800 MHz, provided that the out-of-band emissions are attenuated in accordance with § 95.635.

Suggested Regulatory Changes: LP-LDC Power

§ 95.639 Maximum transmitter power

(f) In the MICS the following limits apply:

- 1) The maximum EIRP for MICS transmitter stations that comply with the access criteria of Section 95.628(a) is 25 microwatts. The maximum EIRP for MICS transmitter stations that operate under Section 95.628(b) is 100 nanowatts.
[Retain remainder of subsection]

Suggested Regulatory Changes: LP-LDC Permissible Communications

§ 95.1209 Permissible communications

MICS stations may transmit non-voice data as permitted below:

- (b) Except in response to a medical implant event, no medical implant transmitter shall transmit except in response to a transmission from a medical implant programmer/control transmitter or a non-radio frequency actuation signal generated by a device external to the body in which the medical implant transmitter is implanted or is to be implanted; provided, however, that medical implant transmitters are not subject to this limitation when operating under the terms of Section 95.628(b).